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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/812,532 | Applicant(s) SCHUL ET AL. | |
| | Examiner Abigail M. Cotton | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005 and 10 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-63 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-63 and 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment after non-final received on September 12, 2005. Claims 57-63 and 65-69 are pending in the application.

Applicant's arguments received September 12, 2005 have been fully considered but they are not persuasive. Accordingly, the rejection of the pending claims under 35 U.S.C. 103(a) over U.S. Patent No. 3,751,569 to Billy Arthur Erickson and U.S. Patent No. 5,502,045 to Miettinen et al. and WO 99/56558 to Wester et al, as made of record in the Office Action mailed April 8, 2005, is being maintained. The rejection is repeated below for Applicant's benefit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson (3,751,569, of record) and Miettinen et al (5,502,045, of record) and Wester et al. (WO 99/56558, of record).

Erickson discloses a clear cooking and salad oil comprising 0.5-10% by weight of the composition of a sterol fatty acid ester, which comprises 100% the particular monounsaturated fatty acid moiety, oleic acid moiety (oleic acid is a known monounsaturated fatty acid, see its chemical structure provided in the Merck Index page 6967). Note that the range of a sterol fatty acid ester in Erickson touches or overlaps with the instant claimed range, 10-30%.

The sterol fatty acid ester employed in the composition therein is β -sitosteryl oleate or stigmasteryl oleate (see particularly Table I at col. 3-4 and Table II at col. 5). See also col. 1 lines 14-18 and 59-65; col. 3 lines 1-30. Thus, the sterol oleic acid esters, β -sitosteryl or stigmasteryl oleate, in the composition therein comprise about 100% oleic acid moiety, which reads on more than 50% monounsaturated fatty acid moiety recited in the claim 57.

Miettinen et al. disclose that sterol fatty acid esters such as fatty acid esters of β -sitosterol and β -sitostanol are useful in compositions for reducing serum cholesterol level. See abstract, col. 1 lines 10-15, col. 3 lines 45-50, col. 4 lines 19-24 and 64-65. The sterol fatty acid ester compositions therein can be added to oils (see particularly in Example 2-4 at col. 5-6), such as 3, 6 and 13% by weight to rapeseed oil (Example 2-3 at col. 5-6), and at about 10-20% weight to margarine (see Example 2-5 at col. 5-6), and especially the rapeseed oil with the ester mixture added remained clear at room

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temperature (known at about 60-70°F) (see col. 6 lines 23-25). Miettinen et al. also disclose that the sterol fatty acid esters therein employed in the compositions are prepared by, for example, β -sitostanol and rapeseed oil fatty acid methyl ester (i.e., interesterifying rapeseed oil fatty acid methyl ester with β -sitostanol to make β -sitostanol rapeseed oil fatty acid esters, see particularly at Example 1 at col. 5 lines 34-47). The conversion rate of esterification therein was achieved to 98% (see col. 5 lines 45-46). Thus, one of ordinary skill in the art would clearly recognize that the unesterified sterol level therein could be 2%, within the instant claim, less than 3, 5, or 10%.

Wester et al. discloses that fatty acid ester of phytosterols and phytosteranols (such as sitosterol, campesterol and stigmasterol) are known to be useful in compositions for reducing serum cholesterol level. See abstract, page 1-3. Wester et al. also disclose that these sterol fatty acid esters compositions can be added to cooking oils and salads oils for the same purpose to reduce serum cholesterol level. See page 4 lines 9-31. Wester et al. also disclose that rapeseed oil employed for making stanol fatty acid esters is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (mainly monounsaturated) (see particularly at page 5 lines 14-17). Wester et al. further disclose that particular sterol fatty acid esters compositions comprise less than 5 or 7% saturated fatty acids (SFAs) (see particularly page 5 lines 8-9, and claims 1-2) and more than 50% PUFA as fatty acid moieties (see particularly page 5 lines 6-7 and claims 1-7).

Erickson does not expressly disclose a clear cooking and salad oil comprising more than 10% by weight of the composition of a sterol fatty acid ester. Mietinen et al. and Wester et al. do not expressly disclose particular sterol fatty acid esters compositions herein comprising more than 50%, about 55-80%, or about 60-70% of fatty acid moiety which are monounsaturated fatty acids (MUFAs) and less 50% polyunsaturated fatty acids (PUFA) moieties.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 10% by weight of the composition of a sterol fatty acid ester, and to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less than 50% PUFA moieties in particular sterol fatty acid esters compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 10% by weight of the composition of a sterol fatty acid ester since more than 10% by weight of the composition of a sterol fatty acid ester to be added in food products such as vegetable oils has been disclosed by Mietinen et al. Moreover, the range of a sterol fatty acid ester in Erickson, 0.5-10%, touches or overlaps with the instant claimed range, 10-30%. The claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In*

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re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP §2144.05 [R-1].

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein since the sterol rapeseed oil fatty acid esters compositions at about 10% by weight are known to be added into the edible oil according to Miettinen et al. Moreover, rapeseed oil is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (including monounsaturated fatty acids and polyunsaturated fatty acids) but mainly monounsaturated fatty acids according to Wester et al. Further, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about 100% oleic acid moiety is known according to Erickson.

Thus, one of ordinary skill in the art would have reasonably interpreted that mainly monounsaturated fatty acids in a high content of unsaturated fatty acids, might be more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids in rapeseed oil. Hence, based on the teachings of Wester et al., the sterol rapeseed oil fatty acid esters compositions of Miettinen et al. would have reasonably been considered to comprise more than 50%,

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about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids.

Further, both Miettinen et al. and Wester et al. teach the same therapeutic usefulness of sterol fatty acid ester compositions for reducing serum cholesterol level and these sterol fatty acid esters compositions can be added to cooking oils and/or salad oils for the same therapeutic purpose. Therefore, one of ordinary skill in the art would have found it obvious to employ sterol rapeseed fatty acid esters compositions comprising more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid moieties and less than 50% PUFA moieties in an edible oil.

Therefore, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Furthermore, the optimization of known amounts of active agents, e.g., monounsaturated fatty acids, polyunsaturated fatty acids, and saturated fatty acids in a known composition to achieve desirable physical properties is considered well within the skill of artisan, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed September 12, 2005 regarding the rejection of the claims under 35 U.S.C. 103(a) over Erickson, Miettinen et al. and Wester et al. have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as discussed above, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation for the instantly claimed sterol fatty acid ester compositions.

Applicants further argue that Erickson teaches away from providing more than 10% of a sterol fatty acid ester, as recited in the instant claims. However, the Examiner respectfully disagrees with this interpretation of the Erickson reference. It is noted that Erickson teaches that a 10% upper limit may be desirable as a practical upper limit to maintain solubility of the various types of sterol esters at refrigerator temperatures (see column 2, lines 35-42, in particular.) However, Erickson et al. further teaches that "solubility levels depend on the carbon chain length of the monocarboxylic acid moiety and its degree of unsaturation", and that for example "oleates are oil soluble at refrigerator temperatures at levels greater than 10%" (see column 2, lines 48-54, in particular.) Thus, while Erickson teaches a preferred sterol ester range, Erickson does not teach against a range of greater than 10%, and in fact teaches that such a range may be suitable for certain types of sterol esters, such as oleates, which are monounsaturated fatty acid esters as in the claim. It is furthermore noted that Miettinen et al. exemplifies the monounsaturated fatty acid esters in an amount of greater than 10%, as discussed above, and thus makes up for any deficiency in the specific teachings of Erickson.

Applicants also argue that Miettinen et al. does not teach a clear oil, as recited in the claims, and instead teaches providing the sterol fatty acid esters in mayonnaise and margarine. However, it is noted that Miettinen et al. clearly teaches that "the rapeseed oil to which the ester mixtures had been added remained clear at room temperature, and no permanent turbidity was observed in it when it was stored at refrigerator

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temperatures" (see Example 3, lines 20-30, in particular.) Thus, despite Applicant's assertion, Miettinen et al. teaches an edible oil that remains clear upon addition of the fatty acid ester composition. Furthermore, since the combined teachings of Erickson and Miettinen et al. and Wester et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the clarity of the edible oil, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Applicants furthermore argue that Wester et al. teaches the desirability of using more polyunsaturated fatty acids (PUFAs) over monounsaturated fatty acids (MUFAs), and thus does not teach providing more than 50% MUFA as claimed. However, it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Miettinen et al. teaches providing rapeseed oil fatty acid esters in an edible oil composition in the amounts recited in the claim, whereas Wester et al. teaches stanol fatty acid esters based on rapeseed oil having "a low content of

saturated fatty acids and a high content of unsaturated fatty acids (mainly monounsaturated)” (see page 5, lines 14-25, in particular.) Erickson also teaches that a sterol ester composition can comprise 100% steryl oleic acid esters, which are monounsaturated fatty acid esters. Accordingly, providing sterol esters based on rapeseed oil and having a high content of mainly monounsaturated fatty acids, such as more than 50%, is obvious over the teachings of Erickson, Mietinnen et al. and Wester et al.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

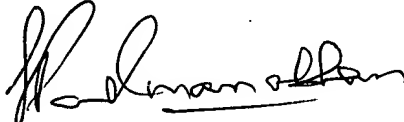
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC


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